RECTILINEAR BIPHASIC WAVEFORM DEFIBRILLATOR OPTION

General Information

Introduction

M Series products are available with an advanced electrical design that provides a unique rectilinear biphasic waveform for defibrillation and cardioversion. With this option, the electrical energy of the defibrillator is delivered in two successive current (voltage) phases of opposite polarity. This type of defibrillation waveform is commonly called "biphasic", as opposed to the earlier "monophasic" damped sine wave common to most commercially available defibrillators.

The ZOLL **M Series** Rectilinear Biphasic Waveform Defibrillator Option produces a proprietary waveform designed for optimal clinical performance and tested extensively in multi-center clinical trials. These clinical trials have demonstrated that the waveform is clinically effective for both defibrillation and synchronized cardioversion.

This insert explains how the **M Series** Rectilinear Biphasic Waveform Defibrillator Option differs from the monophasic damped sine wave output of other **M Series** units. It is to be used in conjunction with the **M Series** Operator's Guide. Important safety information relating to general use of the **M Series** is located in the "Safety Considerations" section of the **M Series** Operator's Guide.

M Series with Rectilinear Biphasic Waveform Defibrillator Option Indications for Use

The ZOLL **M Series** Biphasic Option is to be used only by qualified medical personnel for converting Ventricular Fibrillation (VF), a cardiac rhythm incompatible with life, and/or Ventricular Tachycardias (VT) to sinus rhythm or other cardiac rhythms capable of producing hemodynamically stable heart beats.

In addition, this product is to be used in the synchronized mode only by qualified medical personnel to terminate Atrial Fibrillation (AF) at lower energies and currents than monophasic defibrillators. A qualified physician must decide when synchronized cardioversion is appropriate.

This product is also to be used in the synchronized mode only by qualified medical personnel to terminate Ventricular Tachycardias (VT). A qualified physician must decide when synchronized cardioversion is appropriate.

The Rectilinear Biphasic Waveform (RBW) has been successfully tested in multi-center, prospective, randomized, transthoracic defibrillator VT/VF and AF clinical trials, and proven to defibrillate and cardiovert adult patients at lower energies and currents than existing monophasic devices. The **M Series** Biphasic Option incorporates a broad range of user selectable energy settings some of which are lower than those used during those clinical trials.

There are currently no clinical studies related to the use of the Rectilinear Biphasic Waveform (RBW) in pediatric applications or for direct defibrillation of the heart during open chest surgical procedures.

The AED or advisory function should only be used to confirm ventricular fibrillation in patients meeting the following clinical criteria:

the patient should be unconscious and unresponsive.

the patient should be apneic (not breathing).

the patient should be pulseless.

WARNING

Do not use the unit's AED function on patients under 8 years of age. (Per AHA Guidelines for Adult Cardiopulmonary Resuscitation and AED, 3-5, 1998).

Defibrillator Function

The **M Series** Rectilinear Biphasic Waveform Defibrillator Option is a DC defibrillator capable of delivering up to 200 joules of energy. It can be used for defibrillation or in a synchronized mode for Cardioversion using the R-wave of the patient's ECG as a timing reference. The unit operates with external paddles, or disposable pre-gelled, MFE Pads for defibrillation and cardioversion.

Energy Selection and Displays

Multiple energy levels, and the ability to program initial and subsequent shock energies, allow users to set the **M Series** to either a non-progressive or progressive sequence of shocks.

The **M Series** supports the use of progressive shock sequences to provide an energy reserve, allowing the delivery of a higher energy shock if a lower energy shock fails to terminate the arrhythmia. A sequence of 120J Biphasic, 150J Biphasic and 200J Biphasic would most closely approximate the current AHA recommended escalating energy sequence of 200J, 300J, and 360J for adult defibrillation using a monophasic defibrillator.

When an **M Series** device is equipped with the Biphasic Option, all Energy Displays shown in Section 3, Section 4, and Section 5 (for Manual Defibrillation, Advisory Defibrillation and Automated Defibrillation) of this **M Series** Operator's Guide are modified to add the word "**BIPHASIC**" to the energy display as shown below.

The **M Series** is capable of delivering energy up to 200 Joules with external paddles or Multi-Function Pads. The initial default energy setting for the **M Series** Biphasic option is 120J with external paddles or Multi-Function Pads. The energy settings available with the **M Series** Bi-Phasic device are 1,2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 75, 100, 120, 150 and 200 Joules. Energy settings are selected by using the controls located on the Sternum Paddle or on the front panel of the unit.

The maximum energy available from the **M Series** with Rectilinear Biphasic Waveform Option is 200 Joules. If the operator attempts to increase the energy level above 200 Joules the error message "200 Joules Max Biphasic" will be displayed.

Upon power-up **M Series** units equipped with the Rectilinear Biphasic Waveform Defibrillator Option automatically default to the 120 Joule setting. In units with automatic progressive energy selection enabled, Shock No. 1 is set at 120J; Shock No. 2 is set at 150J and Shock No. 3 is set at 200J. These are the default energy settings. They may be modified following the instructions in the **M Series** Configuration Guide.

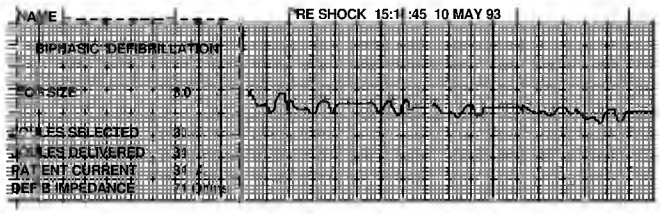
Charge Time

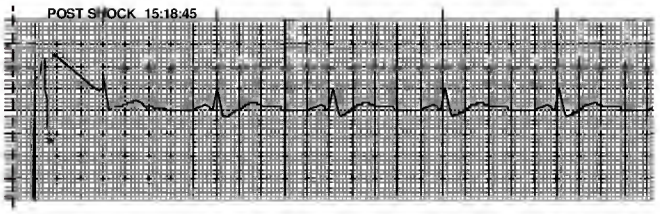
Charge time: < 6 seconds with a new fully charged battery (first 15 charges to 200 Joules). Depleted batteries will result in a longer Defibrillator charge time.

All other operational aspects of the **M Series** Rectilinear Biphasic Waveform Defibrillator are identical to those described in the **M Series** Operator's Guide.

Recorder Printer Annotations

In addition to the information normally printed on the **M Series** recorder and the **M Series** Summary Reports described in Section 2, units equipped with the Biphasic Option will also print Defibrillation Impedance **(DEFIB IMPEDANCE)**, and Delivered Current **(PATIENT CURRENT)**. This information will be included in the **Summary Report** for each defibrillation shock.

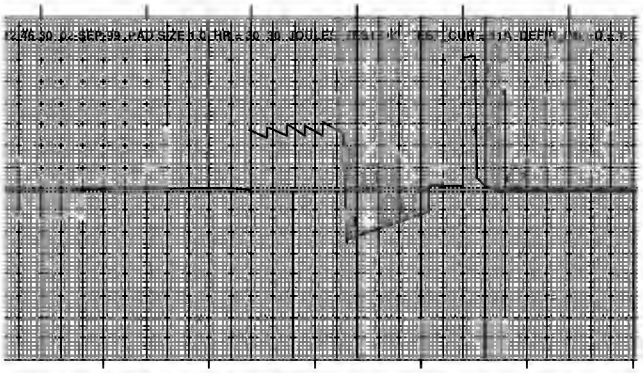




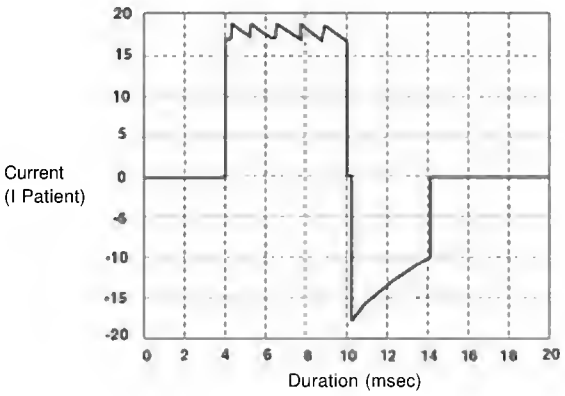
Energy Delivery Test

The energy delivery test for the Biphasic Option is performed at 30 J according to the instructions contained in Section 9 of the **M Series** Operators Guide.

When performing the energy delivery test at 30J the recorder strip should resemble that shown below.



BIPHASIC DEFIBRILLATION PULSE
120 JOULES INTO 50 OHM LOAD



Rectilinear Biphasic Waveform Defibrillator Option Information

The Biphasic Option has been designed to produce a Rectilinear Biphasic Waveform whose shape remains essentially constant from patient to patient by the device.

The Rectilinear Biphasic Waveform consists of a 6 millisecond, essentially constant current first phase followed by a 4 millisecond, truncated exponential second phase. The first and second phases of the defibrillation waveform are of opposite polarity and their amplitudes vary based on the user selected therapeutic energy level. The initial amplitude of this waveform's second phase is approximately equal to the first phase's final amplitude. This waveform has an integrated patient impedance measurement sensing pulse at the beginning of the waveform. The positive and negative phases are separated by 100 µsec. The shape of the waveform's first phase is controlled by electronics and software which compensate for different transthoracic impedances to maintain an essentially constant current throughout the first phase.

When the highest energy setting is selected and patient impedance exceeds 85 ohms, the first phase of the waveform will droop. All other waveform parameters (phase duration, inter-phase delay and integrated impedance measurement sensing pulse) remain the same. The following Rectilinear Biphasic Waveform is produced when the **M Series** with Biphasic option is discharged into a 50Ω load at the default energy setting of 120 Joules. The vertical axis is in amperes; the horizontal axis is in milliseconds. (For more detailed information regarding the parameters of the Rectilinear Biphasic Waveform when discharged into 25Ω, 50Ω, and 100Ω loads at a maximum energy setting of 200 Joules refer to the **Specification** section of this Operator's Insert.

Clinical Trials Results for the M Series Biphasic Waveform:

The Efficacy of ZOLL's Rectilinear Biphasic Waveform has been clinically verified during various studies for defibrillation of Ventricular Fibrillation (VF) / Ventricular Tachycardia (VT) and for synchronized cardioversion of Atrial Fibrillation (AF). Feasibility studies were performed initially for defibrillation of VF/VT (n=20) and synchronized cardioversion of AF (n=21) on two separate groups of patients to ensure waveform safety and energy selection. Subsequently two separate, multi-center, randomized clinical trials were performed to verify the waveform's efficacy. Descriptions of these studies are provided below. All studies were performed using ZOLL defibrillation systems consisting of ZOLL defibrillators, the ZOLL Rectilinear Biphasic Waveform and ZOLL Multi-Function Pads.

A) Randomized Multi-Center Clinical Trial for Defibrillation of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT):

Overview: The defibrillation efficacy of ZOLL's Rectilinear Biphasic Waveform was compared to a monophasic damped sine waveform in a prospective, randomized, multi-center study of patients undergoing ventricular defibrillation for VF/VT during electro-physiological studies, ICD implants and tests. A total of 194 patients were enrolled in the study. Ten (10) patients who did not satisfy all protocol criteria were excluded from the analysis.

Objectives: The primary goal of this study was to compare the first shock efficacy of the 120J Rectilinear Biphasic Waveform with a 200J monophasic waveform. The secondary goal was to compare all shock (three consecutive 120, 150, 170J) efficacy of the Rectilinear Biphasic Waveform with that of a monophasic waveform (three consecutive 200, 300, 360J). A significance level of p=0.05 or less was considered statistically significant using Fischer's Exact test. Also, differences between the two waveforms were considered statistically significant when the customary 95% or AHA recommended 90%* confidence interval between the two waveforms was greater than 0%.

Results: The study population of 184 patients had a mean age of 63±14 years. 143 patients were males. 98 patients were in the biphasic group (ventricular fibrillation/flutter, n=80, ventricular tachycardia, n=18) and 86 patients were in the monophasic group (ventricular fibrillation/flutter, n=76, ventricular tachycardia, n=10). There were no adverse events or injuries related to the study.

The first shock, first induction efficacy of biphasic shocks at 120J was 99% versus 93% for monophasic shocks at 200J (p=0.0517, 95% confidence interval of the difference of –2.7% to 16.5% and 90% confidence interval of the difference of –1.01% to 15.3%).

	Monophasic	Biphasic
1st Shock Efficacy	93%	99%
p-value	0.0517	
95% Confidence. Interval	-2.7% to 16.5%	
90% Confidence Interval	-1.01% to 15.3%	

Successful defibrillation with rectilinear biphasic shocks was achieved with 58% less delivered current than with monophasic shocks (14 ±1 vs. 33 ±7 A, p=0.0001).

The difference in efficacy between the rectilinear biphasic and the monophasic shocks was greater in patients with high transthoracic impedance (greater than 90Ω). The first shock, first induction efficacy of biphasic shocks was 100% versus 63% for monophasic shocks for patients with high impedance (p=0.02, 95% confidence interval of the difference of –0.021% to 0.759% and 90% confidence interval of the difference of 0.037% to 0.706%).

	Monophasic	Biphasic
1st Shock Efficacy (High Impedance Patients)	63%	100%
p-value	0.02	
95% Confidence. Interval	-0.021% to 0.759%	
90% Confidence Interval	0.037% to 0.706%	

A single patient required a second biphasic shock at 150J to achieve 100% efficacy versus six patients for whom shocks of up to 360J were required for 100% total defibrillation efficacy.

Conclusion: The data demonstrate the equivalent efficacy of low energy rectilinear biphasic shocks compared to standard high energy monophasic shocks for transthoracic defibrillation for all patients at the 95% confidence level. The data also demonstrate the superior efficacy of low energy rectilinear biphasic shocks compared to standard high energy monophasic shocks in patients with high transthoracic impedance at the 90% confidence level. There were no unsafe outcomes or adverse events due to the use of the rectilinear biphasic waveform.

* Kerber, R., et. al., AHA Scientific Statement, Circulation, 1997; 95: 1677-1682:
"… the task force suggests that to demonstrate superiority of an alternative waveform over standard waveforms, the upper boundary of the 90% confidence interval of the difference between standard and alternative waveforms must be < 0% (i.e., alternative is greater than standard)."

B). Randomized Multi-Center Clinical trial for Cardioversion of Atrial Fibrillation (AF).

Overview: The defibrillation efficacy of ZOLL's Rectilinear Biphasic Waveform was compared to a monophasic damped sine waveform in a prospective randomized multi-center study of patients undergoing cardioversion of their atrial fibrillation. A total of 173 patients entered the study. Seven (7) patients who did not satisfy all protocol criteria were excluded from the analysis. ZOLL disposable gel electrodes with surface areas of 78 cm^2 (anterior) and 113 cm^2 (posterior) were used exclusively for the study.

Objective: The primary goal of the study was to compare the total efficacy of four consecutive rectilinear biphasic shocks (70J, 120J, 150J, 170J) with four consecutive monophasic shocks (100J, 200J, 300J, 360J). The significance of the multiple shocks efficacy was tested statistically via two procedures, the Mantel-Haenszel statistic and the log-rank test, significance level of p=0.05 or less was considered statistically significant. The data are completely analogous to the comparison of two "survival" curves using a life-table approach where shock number plays the role of time.

The secondary goal was to compare the first shock success of rectilinear biphasic and monophasic waveforms. A significance level of p=0.05 or less was considered statistically significant using Fisher Exact tests. Also, differences between the two waveforms were considered statistically significant when the 95% confidence interval between the two waveforms was greater than 0%.

Results: The study population of 165 patients had a mean age of 66±12 years with 116 male patients.

The total efficacy of consecutive rectilinear biphasic shocks was significantly greater than that of monophasic shocks. The following table displays the Kaplan-Meier (product-limit) "survival" curves for each of the two waveforms. As all patients begin in the failure mode, the estimated life-table probabilities refer to the chance of still being in failure after the k^{th} shock (k=1,2,3,4):

Shock #	Kaplan-Meier Estimate for the Probability of **Shock Failure**	
	Biphasic	Monophasic
0	1.000	1.000
1	0.318	0.792
2	0.147	0.558
3	0.091	0.324
4	0.057	0.208

As can be seen from the table, the Biphasic experience is superior over the entire course of shocks delivered. The one degree of freedom chi-square statistic for the Mantel-Haenszel test is 30.39 (p<0.0001). Similarly, the log-rank test, also a one degree of freedom chi-square statistic, is 30.38 (p<0.0001). The residual number of patients not successfully treated after four shocks is 5.7% for biphasic compared to 20.8% for monophasic.

There was a significant difference between the first shock efficacy of biphasic shocks at 70J of 68% and that of monophasic shocks at 100J of 21% (p=0.0001, 95% confidence interval of the difference of 34.1% to 60.7%).

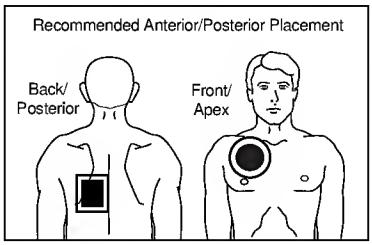
Successful cardioversion with rectilinear biphasic shocks was achieved with 48% less delivered current than with monophasic shocks (11±1 vs. 21±4 A, p<0.0001).

One half of the patients who failed cardioversion after four consecutive escalating monophasic shocks were subsequently successfully cardioverted using a biphasic shock at 170J. No patient was successfully cardioverted using a 360J monophasic shock after the patient had failed cardioversion with biphasic shocks.

Conclusion: The data demonstrate the superior efficacy of low energy rectilinear biphasic shocks compared to high energy monophasic shocks for transthoracic cardioversion of atrial fibrillation. There were no unsafe outcomes or adverse events due to the use of Rectilinear Biphasic Waveform.

Synchronized Cardioversion of Atrial Fibrillation

Cardioversion of Atrial Fibrillation (AF) and overall clinical effectiveness is enhanced by proper pad placement. Clinical studies (refer to above) of the **M Series** Biphasic Defibrillator Waveform Option demonstrated that high conversion rates are achieved when defibrillation pads are placed as shown in the diagram below.



Place the Front (Apex) pad on the third intercostal space, mid clavicular line on the right anterior chest. The Back/Posterior Pad should be placed in the standard posterior position as shown.

Defibrillation and Cardioversion Performance

Caution: The clinical results for the ZOLL Biphasic Defibrillator Waveform Option are based upon the use of ZOLL Multi-Function Pads. The combination of waveform, electrode properties and gel characteristics is essential to achieving efficacy results similar to those described above.

For synchronized cardioversion of Atrial Fibrillation, the combination of waveform, electrode properties, gel characteristics and pad placement is essential to achieving efficacy results similar to those above.

WARNING: Unnecessary skin damage can result from incorrect application or use of a defibrillation pad other than the type recommended.

Additional Messages and TroubleShooting

The following chart lists the messages that may appear on the **M Series** unit relating to the Biphasic Option, why the message appeared, and the action(s) to take.

The operator should become thoroughly familiar with this information before using the device.

Message	Possible Cause(s)	Recommended Action(s)
200 J MAX BIPHASIC	Appears when trying to select an energy higher than 200 Joules.	No higher energy is available. Use 200J setting.
BRIDGE TEST FAILED	Biphasic module not operating properly while charging.	Try charging again. Attempt to clear the message by turning the Selector Switch to OFF then back to the desired operating mode. If Fault persists contact ZOLL Technical Service Department.
BRIDGE SHORT	Current higher than expected was detected.	Ensure pads/paddles are used properly. Attempt to clear the message by turning the Selector Switch to OFF then back to the desired operating mode. If Fault persists contact ZOLL Technical Service Department.

Additional Specifications and Changes

General

Refer to M Series Operator's Guide for ALL Specifications except the following:

Waveform:	Rectilinear Biphasic
Energy Settings:	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 75, 100, 120, 150, 200
Charge Time:	Less than 6 seconds with a new fully charged battery (first 15 charges at 200J)
Messages:	"200 J MAX BIPHASIC", "BRIDGE TEST FAILED", "BRIDGE SHORT"
Operating Time:	For a new, fully charged battery pack at 20°C: 40 defibrillator discharges at maximum energy (200J), or 2.75 hours minimum of continuous ECG monitoring, or 2.25 hours of continuous ECG monitoring/pacing at 60 mA, 80 beats/min.

The following table shows the Rectilinear Biphasic waveform's characteristics when discharged into 25Ω, 50Ω, and 100Ω loads at a maximum energy setting of 200 Joules.

	Discharged into 25Ω Load	**Discharged into 50Ω Load**	**Discharged into 100Ω Load**
I_{MAX} 01 = First Phase Maximum Initial Current	30 A	26 A	21 A
I_{AVG} 01 = First Phase Average Current	27 A	23 A	16 A
TD 01 = First Phase Duration	6 ms	6 ms	6 ms
T_{INTD} = Interphase duration between first and second phases.	100 µs	100 µs	100 µs
I_{MAX} 02 = Second Phase Maximum Initial Current	26 A	21 A	14 A
I_{AVG} 02 = Second Phase Average Current	15 A	15 A	12 A
TD 02 = Second Phase Duration	4 ms	4 ms	4 ms